

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. DISPOSITION OF THE CLAIMS**

Claims 15 and 17 are requested to be canceled.

Claims 16, 18-19, and 23-24 are currently being amended.

The amendments add no new matter.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 16-22 are now pending in this application.

Applicants thank the Office for extending examination to include all species of the claimed invention. Office Action, page 2, paragraph 3.

**II. MISCELLANEOUS OBJECTIONS**

Applicants have amended the title to replace the objectionable phrase “weak patients” with “low-responder patients”. Office Action, page 3, paragraph 6.

Applicants have added appropriate section headings. Office Action, page 3, paragraph 7.

Applicants have amended claims 23-24 to obviate the objections for improper Markush format and recitation of “anti-virals”. Office Action, page 4, paragraph 8.

### **III. INDEFINITESS OF THE CLAIMS**

Applicants have canceled claim 15 and have amended claim 23 to obviate the indefiniteness rejections. Office Action, page 5, paragraphs 10.A. and 10.B.

Applicants have removed the terms relating to “in particular”, “preferably”, and “for example”, to obviate the corresponding rejection. Office Action, page 5, paragraphs 10.C.

Applicants have amended claims 23-24 to obviate the corresponding rejection for the term “coagulation factors”. Office Action, page 5, paragraph 10.D.

### **IV. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled and lacking written description support (possession). Applicants respectfully traverse, and have obviated both rejections by amendment.

#### **A. Nonenablement**

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled. Applicants respectfully traverse.

The Office asserts as follows (Office Action, page 7, paragraph 12):

[T]he specification, while being enabling for methods of treating a specific disease by administering a specific corresponding antibody (such as e.g. B-cell lymphoma and anti-CD20 antibody), does not reasonably provide enablement for a method of treating a disease with an unrelated antibody (such as the great majority of diseaseantibody combinations recited e.g. in claims 15 and 23), or a method of treating any disease by administering a generically recited antibody (such as recited e.g. in claim 15).

The Office further asserts as follows (emphases added; Office Action, page 7, first paragraph):

One of skill in the art is aware that for such treatment to be successful, the antibody must be specific to an antigen restricted to the cell type involved in the pathogenesis of the

particular disease. Antibodies specific to antigens present on other cell types would cause cytotoxicity of cells unrelated to the disease, and thus would be ineffective or harmful.

Therefore, one of skill in the art would understand that although certain specific disease/antibody combinations, such as those disclosed in Table 1 at pages 17 - 18, appear to be enabled, the vast majority of possible combinations cannot be practices as claimed without undue experimentation.

The Office acknowledges, by the highlighted text in the passage quoted above, that the disease/antibody combinations in Table 1 would be recognized as enabled by a person of ordinary skill in the art.

Applicants submit that a person of ordinary skill in the art would understand these combinations as representing the scope of the claimed invention. Further, a person of ordinary skill in the art would recognize “ineffective or harmful” combinations as not encompassed by the present claims. The claimed invention is a “method for treating” the recited conditions, and is necessarily limited to recognizably operative embodiments.

The present specification provides the following guidance:

Thus, for a subpopulation of so-called “low-responder” patients in relation to the polymorphism of amino acid 158 of CD16 or another polymorphism associated with this polymorphism, the efficacy of the treatment is better with the optimised antibodies of the invention, and is similar to that of so-called “high-responder” patients.

We show that the functional activity of the optimised monoclonal antibodies is related to that of therapeutic polyclonal antibodies. Thus, in some therapeutic trials, the polyclonal antibodies can be used as controls in tests on the efficacy of monoclonal antibodies of different origins. This makes it possible to select monoclonal antibodies intended for the treatment of subpopulations of low-responder patients.

Another alternative consists of performing a comparison with the antibodies available on the market, in particular antibodies being developed, antibodies for which marketing authorisation has been obtained, or antibodies for which the clinical trials were stopped, and shown to be ineffective or to produce 20 adverse effects at the doses administered.

Accordingly, Applicants submit that the present specification sufficiently enables the claims in full compliance with § 112, first paragraph.

**B. Written Description**

The claims stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description support (possession). Applicants respectfully traverse.

The Office asserts as follows (Office Action, page 7, paragraph bridging pages 7-8):

In the absence of a disclosure in the instant specification of sufficiently detailed, relevant identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, the skilled artisan cannot envision all the contemplated antibodies, antigens, and inhibitors encompassed by the breadth of the instant claims.

Here, the specification provides sufficient “correlation between function and structure” in demonstrating via Examples 1-4 as illustrated in FIGs. 1-4, that the function of enhancing lysis results from the structure of antibodies that are “over 60% for the forms G0 + G1 + G0F + G1F” and “forms G0F + G1F are lower than 50%”.

Accordingly, Applicants submit that the present specification sufficiently demonstrates “possession” of the invention in full compliance with the written description requirement of § 112, first paragraph.

**V. OBVIOUSNESS-TYPE DOUBLE PATENTING (ODP)**

The claims stand rejected for non-statutory obviousness-type double patenting over co-pending application 10/575,333. Applicants request that this rejection be held in abeyance, pending indication of allowable subject matter.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10-DEC-2008

By \_\_\_\_\_



FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 295-4059  
Facsimile: (202) 672-5399

Rouget F. Henschel  
Attorney for Applicant  
Registration No. 39,221